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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/510,267 | 03/14/2005 | Martin Brouillette | 40128/02301 | 8750 |

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| EXAMINER |
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HALL, DEANNA K

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| ART UNIT | PAPER NUMBER |
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3767

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/09/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/510,267

Applicant(s)

BROUILLETTE ET AL.

Examiner

Deanna K. Hall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :October 5, 2004; November 7, 2005; March 10, 2006.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "producing" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984). Claims 4-10 and 33 are rejected due to their dependence upon claim 1-3.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellhouse et al. (US 5,630,796) ("Bellhouse").** Bellhouse discloses a method for needless injection of a liquid substance in the skin or other target tissue comprising:

Producing droplets of the liquid substance **28; C4 L14-16** and directing and accelerating the droplets of liquid substance toward the surface of the patient's skin or

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other target tissue at a velocity sufficiently high to inject the droplets of liquid substance in the patient's skin or other target tissue **See abstract.**

Producing a high velocity jet of gas which entrains the droplets of liquid substance which are then guided to the surface of the patient's skin or other target tissue for injection **C1 L35-44**. Wherein the high velocity jet of inert gas comes from supplying pressurized gas **C5 L46-55** from a gas reservoir **11** to a convergent-divergent **35,37**.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellhouse in view of Long (US 6,808,246).** Bellhouse shows as discussed above.

The object of Bellhouse's invention is to transdermally deliver particles of a therapeutic agent entrained in a supersonic gas flow **C1 L30-44**. Bellhouse does not directly show the mechanism for generating the liquid droplets; rather, Bellhouse shows providing the encapsulated liquid drug in a capsule **28**, **C4 L14-16**. Long, in the analogous art, teaches a droplet generator and acceleration in a high velocity jet of gas. In doing so Long teaches: a pressurized liquid reservoir which forces liquid through a perforated membrane **40**, **C5 L28-34** to produce the droplets of liquid substance which are then

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entrained in the high velocity jet of gas **C1 L19-25; C5 L25-28**. Long further teaches a valve **58** to control the gas flow **C3 L66- C4 L3** and a valve **114** to control the fluid pressure in the liquid chamber **C5 L25-28**. The perforated membrane **40** comprises a metallic or polymeric membrane with at least one micro-orifice **C5 L10-34**. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Bellhouse with the droplet generator components as taught by Long for producing liquid droplets from a continuous stream of pressurized liquid **C1 L19-25**.

Bellhouse further discloses an intermediate chamber **25** between the pressurized gas supply and the inlet of the convergent-divergent **Figs. 1, 5, 6** with a valve to control the supply of pressurized gas to the intermediate chamber and from the intermediate chamber to the convergent-divergent **C14 L26-35**. This intermediate chamber **25** can also be considered to be interposed between the pressurized gas supply and the liquid reservoir **28**. Bellhouse further discloses the liquid chamber **28** having a movable wall or burstable membrane to displace the liquid by means of a piston **C6 L53-67**. The valve releasing the gas flow to the convergent-divergent is a mechanical valve comprising a piston, spring or plunger **C6 L53-67**. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate electronic rather than mechanical valves, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 8:00am-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

dkh

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER



Deanna K. Hall
Examiner
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